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First Named Inventor:	JAPUNTICH, DANIEL A.		
Application No.:	09/680,465	Group Art Unit:	3743
Filed:	October 3, 2000	Examiner:	Aaron J. Lewis
Title:	FIBROUS FILTRATION FACE MASK HAVING A NEW UNIDIRECTIONAL FLUID VALVE		

REPLY BRIEF

Commissioner for Patents
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CERTIFICATE OF TRANSMISSION
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I hereby certify that this correspondence is being facsimile transmitted to the U.S. Patent and Trademark Office on:
February 11, 2004
Date
Signed by: Susan M. Dacko

Dear Sir:

Applicants submit this Reply Brief in response to the Examiner's Answer mailed December 16, 2003. Applicants respectfully dissent from a number of positions taken by the Examiner. Each of the Examiner's positions is reproduced below in quotes, followed by applicants' rebuttal argument.

1. Examiner's Answer at page 13, 5th Paragraph

"Applicant's arguments filed 02/07/2003 have been fully considered but they are not persuasive. Applicants' argument that McKim constitutes nonanalogous art because it has been held that a prior art reference must either be in the field of applicants endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned in order to be relied upon as a basis for rejection of the claimed invention. ... In this case, this is submitted that one of ordinary skill would look to the art of valves (which includes McKim (' 618)) to address problems associated with the effectiveness of valve seating of a valve element which is used for controlling the direction of flow of breathable air through such a valve. McKim clearly addresses the problem of effectiveness of valve seating by non-aligning the valve flap retaining surface and the seal surface relative to each other thereby providing effective seating without float or bounce after each opening (col. 1, lines 64-72)."

Applicants' Response:

Applicants respectfully assert that the Examiner is incorrect in finding the facts and is incorrect in applying the law.

In regard to an incorrect finding of facts, the record, contrary to the Examiner's position, does not contain any evidence of a desire to provide "effective seating without float or bounce after each opening" of an exhalation valve. As applicants have demonstrated repeatedly during this prosecution, this position is merely a statement of opinion, wholly unsupported by the evidence of record. Nowhere does the record show that "float or bounce" is a problem that needs to be overcome in the exhalation valve art. In fact, the evidence establishes exactly the opposite: it shows that "float or bounce" is not a problem that needs to be dealt with by persons who design exhalation valves.

In regard to the law, the second part of the two-part test for determining whether a reference is analogous does not look only at the purpose of the device described in the cited reference. The test looks at the purposes of **both** the claimed invention and the device described in the prior art document, and it compares these two purposes.[1] The Examiner has not examined both purposes and has not made such a comparison. The Examiner therefore has committed legal error in assessing whether McKim is analogous. The Federal Circuit held that the USPTO needs to consider the purposes of the reference disclosure *and* the invention in determining whether a reference is reasonably pertinent to the particular problem that confronted the inventor.[2] In *In re Clay*, the Federal Circuit found the cited reference to be not analogous when the prior art was directed to different purpose than the claimed invention.[3]

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[1] Because the Examiner does not dispute the fact that McKim does not reside in applicants' field of endeavor, we only need to evaluate McKim under part (2) of the test.

[2] *In re Clay*, 23 USPQ2d 1058, 1061 (Fed. Cir. 1992) ("A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem. **Thus, the purposes of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve.** If a reference disclosure has the same purpose as the claimed invention, the reference relates to the same problem, and that fact supports use of that reference in an obviousness rejection. An inventor may well have been motivated to consider the reference when making his intention. **If it is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it (emphasis added)")**

[3] *See, Clay*, 23 USPQ2d at 1601 ("Moreover, the subterranean formation of Sydansk is not structurally similar to, does not operate under the same temperature and pressure as, and does not function like Clay's storage tanks."); *see also, SRI Int'l, Inc. v. Advanced Tech. Lab.*, 45 F.3d 443, 445 (Fed. Cir. 1995) ("The problem Green solved was how to compensate for changes in the spectral distribution of the return ultrasonic signal, with time or depth of penetration into a living organ, for enhanced image resolution and/or signal to noise ratio. The Minton reference, which relates to seismic prospecting circa 1946, almost thirty years prior to Green's filing date, would not have logically commended itself to Green's attention in considering how to compensate for changes in the spectral distribution of a received ultrasonic signal in an object such as a body part."); *In re Green*, 22 F.3d 1104, 1105 (Fed.

When the law is properly applied in this case, and the McKim disclosure is carefully reviewed along with the purpose of applicants' invention, the Board will note that the McKim valve does not share the same purpose as applicants' invention, it does not operate under the same temperature and pressure, and it does not function like applicants' invention. Float or bounce is a problem that occurs when 2-cycle engines operated at high rpms (10,000 to 12,000 rpms). It has not been a problem that occurs in exhalation valves, which open and close in cadence with a person's breathing (about 20 to 60 cycles per minute). In addition, internal combustion engines operate at extraordinarily higher temperatures and pressures than a person's exhalation breath and are not powered by a person's lungs but by gasoline combustion. Finally, McKim's valve is used for intake into a combustion cylinder while the present valve is used for exhaust from the interior gas space of a mask. A summary of the facts in *In re Clay* have been provided in applicants' Appeal Brief for ease of reference.

2. Examiner's Answer at page 14, first full paragraph

"Applicants' argument that the valve of McKim lacks the required flexibility of applicant's invention is disagreed with because McKim (figs. 1 and 3) illustrates flexibility of the valve flap (14)."

Applicants' Response:

McKim may illustrate in its figs. 1 and 3 that its *valve reed* can be bent, but this illustration does not mean that the reed valve 14 in McKim qualifies as a "flexible flap" as that term would be reasonably interpreted by a person of ordinary skill, consistent with a reading of applicants' specification. Any interpretation of McKim, which would have its valve reed 14 qualify as a flexible flap, would either be the result of an incorrect reading of McKim's scope and content or an overbroad unreasonable interpretation of the term "flexible flap". The record

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Cir. 1994) ("A person of ordinary skill in the aircraft vane art simply would not find a 1919 reference about broken blades in a pugging mill reasonably pertinent to this problem."); *In re Butera*, 1 F.3d 1252, 1253, 28 USPQ2d 1399, 1400 (Fed. Cir. 1993) ("Butera's design is for air fresheners and insect repellents, while Hodge's is for metal ball anodes. The design of Hodge involves a different type of article from Butera's design and it is not analogous. One designing a combined insect repellent and air freshener would therefore not have reason to know of or look to a design for a metal ball anode. Since Hodge is not analogous, the Board clearly erred in finding Hodge to be citable as prior art. Therefore there was no basis for rejecting Butera's claimed design as obvious."); *Wang Laboratories, Inc. v. Toshiba Corp.*, 993 F.2d 858, 864, 26 USPQ2d 1767, 177_ (Fed. Cir. 1993) ("Wang's SIMMs were designed to provide compact computer memory with minimum size, low cost, easy repairability, and easy expandability. In contrast, the Allen-Bradley patent relates to a memory circuit for a larger, more costly industrial controller. SRAMs were used by Allen-Bradley because of their intended industrial environment. According to Dr. Frey, size was not a consideration in the Allen-Bradley work. Thus, there is substantial evidence in the record to support a finding that the Allen-Bradley prior art is not reasonably pertinent and is not analogous.").

shows that McKim's valve reed 14 is "of sheet material, such as, for example, shim stock" and would not be able to be bent in response to gravity or the breath of a person.[4] Thus, unless the Examiner can supply the record with evidence to demonstrate otherwise, the Examiner must be giving an unreasonable construction to the meaning of "flexible flap".

3. Examiner's Answer at page 14, first full paragraph

"Further, the manner of bending illustrated in figs. 1 and 3 of McKim is consistent with appellants definition of a '...the flap can form or bend in the form of a self-supporting arc when secured at one end as a cantilever and view from a side elevation...'. (sic)"

Applicants' Response:

The manner of bending McKim's rigid valve reed is not consistent with applicants' definition. Applicants' invention uses a flexible flap that can deform or bend in response to gravity or pressure from a person's breath. McKim uses a mechanical means to cause its valve reed 14 to be bent. The force that McKim uses, as described by Betts, is on orders of magnitude greater than the forces that are used to bend flexible flaps in exhalation valves:

> Since 1965, 2-cycle engines that I have either constructed or work on used the reed valve of varying degrees of stiffness. None of the reed valves that I have encountered, however, where "flexible" as that term has been defined in the above-captioned patent application and recited in paragraph 4 above. Reed valves that are used on 2-cycle engines can bend when exposed to force such as shown in Fig. 3 of the McKim patent. The reed valves, however, are not so flexible that they will bend in the form of a self-supporting arc when secured at one end as a cantilever. Reed valves do not bend in the form of such an arc in response to the mere force of gravity. If the valves were constructed to have that degree of flexibility, the 2-cycle engines in which they were used would surely not be operative. If secured at one end as a cantilever and having a free end that projects from the point of securement, a reed valve would project in an essentially straight line when viewed from a side elevation. The degree of stiffness that reed valves possess are orders of magnitude greater than flexible flaps that are used on exhalation valves.[5]

If the McKim valve could be so easily bent, its 2-cycle engine would be inoperative. When the meaning of applicants' term "flexible flap" is given an interpretation that is not just the broadest construction possible but is instead the broadest *reasonable* interpretation, *consistent with* the

[4] See Richard Betts' Declaration.
[5] *Id.* at paragraph 5.

specification, as required by law, there can be no other conclusion other than that McKim's valve reed 14 would not qualify as a flexible flap.

4. Examiner's Answer at page 14, lines 10-12

"Finally, no particular degree of flexibility is quantitatively and/or structurally defined in any manner which is unobvious over the prior art combination of Simpson et al. as modified by McKim."

Applicants' Response:

Applicants have defined the term flexible to mean that the flap can "deform or bend in the form of a self-supporting arc when secured at one end as a cantilever and viewed from a side elevation" (p. 7, lines 22-24). Thus, it is incorrect to say that no degree of flexibility is quantitatively defined.

5. Examiner's Answer at page 14, 2nd full paragraph

"As to the Bowers, Fabin, and Bett's affidavits, the individual arguments that McKim constitutes nonanalogous art because it has been held that the prior art reference must either be in the field of applicants endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. ... In this case, it is submitted that one of ordinary skill would look to the art of valves (which includes McKim ('618)) to address problems associated with the effectiveness of valve seating of a valve element which is used for controlling the direction of flow of breathable air through such a valve. McKim clearly addresses the problem of effectiveness of valve seating by non-aligning the flap retaining surface and the seal surface relative to each other thereby providing effective seating without float or bounce after each opening (col. 1, lines 64-72)."

Applicants' Response:

The Examiner appears to hold that McKim is analogous because it satisfies the second part of the two-part test for ascertaining whether a reference is analogous. That is, the Examiner believes that McKim is reasonably pertinent to the particular problem that confronted the inventor. This position is erroneous for a number of reasons. Firstly, the problem that confronted applicants did not pertain to the effectiveness of valve seating, namely, preventing

valve flutter or float during closing. Applicants sought to produce a valve that operated under minimal pressure drop and that remained closed under any orientation of the valve. Applicants did not seek to produce a valve that eliminated float or bounce problems. Why would applicants try to produce a valve that lacked float or bounce problems when no such float or bounce problems existed in the exhalation valve art? For some reason, the Examiner refuses to address this issue. Secondly, the second part of the two-part test for determining whether a reference is analogous does not look only at the purpose of the prior art reference. The test ascertains whether the reference "logically would have a commended itself to an inventor's attention in considering his problem."[6] In making this determination, the reviewing courts have instructed the Patent Office that it should evaluate the purposes of the invention and the prior art and determine whether those purposes are the same and whether they address the same problem. As indicated above, applicants' invention addresses an entirely different purpose and solves an entirely different problem from McKim. As such, McKim would not have been a reference that would have logically commended its attention to a person ordinary skill in the exhalation valve art.

7. Examiner's Answer at paragraph bridging pages 14 and 15

"Appellants' argument that the valve of McKim lacks the required flexibility of applicant's invention is noted; however, it is submitted that the valve of Simpson et al., being an exhalation valve, exhibits structure which is fully capable of providing such a function. Further, no particular degree of flexibility is quantitatively and/or structurally defined in any of the claims of the instant implication."

Applicants' Response:

Of course, it is always possible to pick and choose certain features from different references in reconstructing an invention. Even if we assume that Simpson discloses a flap material that meets the requirements of applicants' invention, this does not mean that McKim is analogous or that the record exhibits evidence of a teaching, suggestion, or motivation to combine McKim and Simpson. Applicants cited the stiff valve material of McKim as evidence that the teachings of McKim could not be so easily transferred to Simpson. Because Simpson's

[6] *In re Clay*, 23 USPQ2d 1058, 1061 (Fed. Cir. 1992).

flap material is made from an entirely different material than the McKim reed valve, a person ordinary skill could not be sure that the structure of the McKim valve could be suitably incorporated into the Simpson valve to satisfy all the needed performance parameters of an exhalation valve for a filtering face mask. Only after applicants' conception, and after applicants' actual reduction to practice of their conception, and after the testing of it in its fully operative form, were the inventors able to discover that their new valve provided extraordinary performance in a suitably operative manner for use as an exhalation valve on a filtering face mask.

In regard to the second sentence quoted above, Applicants define the term "flexible" to mean that the flap can deform or bend in response to gravity or exhalation pressure. The record shows that McKim's valve reed 14 "of sheet material, such as, for example, shim stock" would not be able to bend in response to gravity or breath from a person. As such, the McKim reed valve would be inoperable in applicants' invention. It may be true that the McKim valve exhibits "flexibility" under another construction of this term. Applicants, however, have not defined the term "flexible" to be so broad as to encompass shim stock that does not bend in response to the force of gravity or a wearer's exhalate. McKim (in its figs. 1 and 3) shows that its valve reed can be bent, but this bending is done in response to a strong external mechanical force. Thus, unless the Examiner can supply the record with evidence to demonstrate that the McKim flap bends like applicants', it would appear that the Examiner is improperly interpreting McKim or is giving an unreasonable interpretation to the meaning of applicants' "flexible flap" language.

8. Examiner's Answer at page 15, 1st full paragraph

"Applicants arguments that the prior art does not provide the benefits of applicants invention is disagreed with because the prior art does teach the claimed structure of the instant application and as such, is fully capable of providing the so-called benefits."

Applicants' Response:

Yes, if you reproduce applicants' invention by selecting various elements from various prior art references, you will produce a structure that achieves the same benefits. So what? This is beside the point, and it has no bearing on a proper obviousness determination. Further, applicants do not argue that a valve identical to applicants' invention would not achieve the same results. What applicants argue is that neither Simpson nor McKim provides any suggestion of

the benefits that the present invention can provide. Simpson, for example, accepts the deleterious performance of his valve by suggesting the use of an antechamber to protect the user from valve leakage. McKim, being in the field of two cycle engines, has no concern for achieving a low pressure drop while maintaining a closed valve under any orientation. Applicants have demonstrated that a very low pressure drop valve, which valve is capable of remaining closed under any orientation, can be provided for filtering face masks. The new structure, and the benefits that stem from it, provide very good evidence of nonobviousness.

9. Examiner's answer at page 15 third full paragraph

"Accordingly, the affidavits by Bowers, Fabin, and Betts are insufficient to overcome the prior art rejection set forth hereinabove based upon a conclusion that they do not believe that one of ordinary skill would be motivated to combine the teachings of McKim with Simpson et al. to achieve the valve of the instant invention. It is submitted that one of ordinary skill having possession of the prior art to Simpson et al. and McKim which clearly teaches nonaligned mounting of the valve flat in order to achieve effective ceiling would suggest in answer to the problem of how to prevent accidental valve opening between inhalation in exhalation."

Applicants' Response:

The Examiner misstates the reason applicants presented the Bowers, Fabin, and Betts affidavits/declarations in this case. The evidence set forth in these affidavits/declarations was presented to demonstrate that McKim resides in a nonanalogous art. The documents were not presented to show lack of motivation to combine. The affidavits/declarations show (1) that McKim does not reside in applicants' field of endeavor and (2) that McKim would not have logically commended itself to applicants' attention. In any case, the burden is not upon applicants to demonstrate that a person of ordinary skill would not have been motivated to combine Simpson with McKim. The burden is on the United States Patent and Trademark Office to present the motivating evidence for making the combination. This evidence has yet to be presented, and therefore no *prima facie* case of obviousness has been established. As such, the obviousness rejection cannot be properly sustained under the terms of 35 USC § 103.

10. Examiner's Answer at page 15, last paragraph

"Applicants' assertions that the valve of fig.2 of Simpson et al. dangles open are not persuasive. The mask of Simpson et al. is specifically intended to filter gaseous or vaporous contaminants and particulate contaminants (page one, lines 16-28 and lines 79-84) and is intended for use in noxious atmospheres (page one, lines 58 +). The valve of fig. 2 is expressly disclosed as opening responsive to wearer's exhalation (page two, lines 38-50). One of ordinary skill would not conclude that the exhalation valve of fig. 2 would dangle open under any conditions of proper use because the mask would not function as it is disclosed and intended to operate."

Applicants' Response:

The Examiner is reviewing the Simpson patent from the perspective of a person who has read applicants' specification rather than from the state-of-the-art that existed at the time the Simpson patent was published. Because Simpson does not impose a preload on its flapper valve 13 shown Figure 2, because Simpson places the valve 12 on the top portion 1of the mask (figure 1), and because Simpson suggests the use of an antechamber to prevent harmful contaminants from leaking into the mask through the exhalation valve (p. 1, lines 58-64), it is clear that the Simpson valve does not remain closed under any orientation of the mask. Thus, although it may be apparent that a person of ordinary skill would want to design a flapper valve that remained closed under all conditions after reading applicants' specification, it certainly was not apparent to Simpson in 1980. Although the Examiner opines that such a valve would have been created by Simpson, the record does not reflect any evidence of this. Indeed, the record reflects the exact opposite. The Examiner's "reasoning" thus does not derive from Simpson but rather is a viewpoint that was arrived at after reading applicants' specification.

11. Examiner's answer at page 16, first full paragraph

"To the extent, if any, that the valve of fig. 2 of Simpson et al. may dangle open, the combination of Simpson et al. as modified by McKim would assure that the valve flap of Simpson et al. as modified by McKim would remain sealed against its seat due to its prestressed configuration until a wearer exhaled."

Applicants' Response:

Of course a hindsight reconstruction of applicants' invention would create a product that performs similarly. But a hindsight reconstruction relieves the United States Patent and Trademark Office of establishing that McKim resides in an analogous art and of establishing that the prior art presents evidence of a sound reason to combine Simpson with McKim. Only if you ignore the test for determining whether a reference is analogous and only if you ignore the requirement that there be a teaching, suggestion, or motivating factor for combining the separate references can you make the combination suggested by the Examiner to arrive at the complete construction of applicants' invention.

12. Examiner's Answer at page 16, 2nd full paragraph

"Applicants' assertion that record is devoid of any teaching, suggestion or motivation to combine the prior art to Simpson et al. and McKim is not accurate. As set forth in the body of the rejection, the reason for combination of Simpson et al. with McKim is because it would have provided for quick effective seating without float or bounce after each opening as taught by McKim (col. 1, lines 64-72)."

Applicants' Response:

The Examiner's position confuses unsupported opinion with evidence. As applicants have demonstrated repeatedly in this prosecution, persons skilled in the art of designing exhalation valve's do not search for solutions to eliminating float or bounce. Applicants have supported this position with uncontroverted documentary evidence in the form of Affidavits and Declarations signed by persons skilled in the field of designing such valves. The record also is devoid of a single reference that states, either explicitly or implicitly, that exhalation valves exhibit float or bounce problems. Because applicants have fully established that persons who design exhalation valves do not encounter — much less look for solutions to — "float or bounce" problems, the record accordingly lacks any motivating evidence for making the combination asserted in the rejection. Nonetheless, the Examiner maintains the position that a person of ordinary skill in the art of designing exhalation valves would have used the teachings of McKim's gasoline engine reed valve for purposes of eliminating float or bounce in an exhalation valve,

despite no evidentiary authority in the record, other than mere opinion.[7] As the Board is aware, bald conclusions like this are not *evidence* that can be properly relied on to sustain a rejection based on a combination of references.[8]

13. Examiner's Answer at page 16, third full paragraph

"Applicants' assertion that Simpson et al. and McKim each present very good evidence of a lack of motivation to combine their respective teachings because no one of ordinary skill in the respirator art has made use of the teachings of McKim in making an exhalation valve is not accurate because examples of the use of the manner of mounting valves as taught by McKim do exist in the respirator art. The mounting of flapper valves in the respirator art by clamping a stationary portion of the flap in a different plane than the sealing surface (i.e. seat) resulting in a curved configuration which physically biases a free end of the valve to a closed position is well known (see fig. 3 of Simpson et al.). Another example is seen in the prior art to Matheson (cited but not applied) U.S. Patent 2,999,498, fig. 8 and col. 1, lines 38-46.

Applicants Response:

The Examiner's position is inaccurate; the scope and content of the prior art have again been mischaracterized. Simpson does not disclose a flapper valve in its fig. 3. Figure 3 illustrates a button-style valve. Additionally, the mounting surface of the Simpson fig. 3 valve resides in the same plane as the sealing surface. Thus, there is no bias on the flap in any event.

Matheson (U.S. 2,999,498) does not describe an exhalation valve; it describes an inhalation valve. And there is no disclosure in Matheson, which disclosure shows that its flap is biased towards the seal surface. In fact, Matheson teaches the opposite. Figure 8 of Matheson is reproduced below for east of reference.

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[7] "Unsupported" is probably not the best word to use in this sentence. The Examiner's view is not merely "unsupported": it is actually "false". This falsity has been established by Bowers and Fabin when they unequivocally stated that float or bounce is not a problem that is confronted by persons who design exhalation valves.

[8] *See, In re Dembiczak*, 50 USPQ 1614, 1617 (Fed. Cir. 1999) ("Broad conclusory statements regarding the teachings of multiple references, standing alone, are not 'evidence'."); *see also, Lee*, 61 USPQ2d at 1434 ("With respect to Lee's application, neither the examiner nor the Board adequately supported the selection and combination of the Nortrup and Thunderchopper references to render obvious that which Lee described. The examiner's conclusory statements that 'the demonstration mode is just a programmable feature which can be used in many different device[s] for providing automatic introduction by adding the proper programming software' and that 'another motivation' would be that the automatic demonstration mode is user friendly and it functions as a 'tutorial' do not adequately address the issue of motivation to combine. The factual question of motivation is material to patentability, and could not be resolved on subjective belief and unknown authority.").

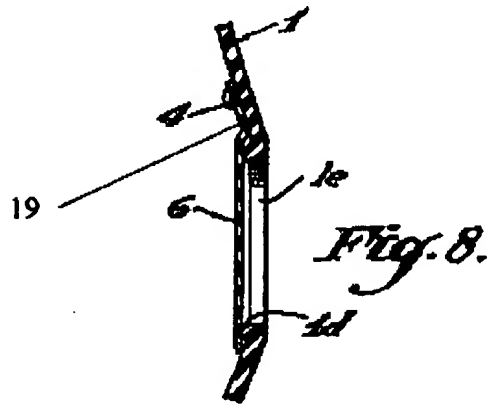

Fig. 8.

As shown, the Matheson valve has a "kink" in it at the location identified by applicants' attorney using numeral 19. This "kinked" portion would not cause the free portion of the flap to be pressed towards the seal surface so that it may reside closed under any orientation of the valve. Indeed, Matheson realizes this by indicating that its valve requires gravity to keep the flap closed:

> An important feature of suspending diaphragms 6 and 7 from the top only without further support along the marginal portions is that gravity will assist in keeping the diaphragms in their normal downward and seated positions as shown in Fig. 8.[9]

Further, inhalation valves, unlike exhalation valves, close during an exhalation in response to the exhalation pressure. And air that passes through the inhalation valve must first pass through the filtration media in the filter cartridge. Leakage therefore is not an issue. Thus, there is no need to place a pre-stress on the valve to keep it closed under any orientation of the mask. The inhalation valve closes forcibly when a wearer exhales (see the '498 patent to Matheson at column 4, lines 1-8) so that the exhaled air is quickly forced out of the exhalation valve rather than through the filtration media.

14. Examiner's Answer at page 17, 4th paragraph

"Appellent's arguments regarding any pre-stress on the valve of Simpson et al. hinge on speculation of a possibility that valve flap (15) of Simpson et al. might 'droop' away from the valve seat. There is no support in the disclosure of Simpson et al. which forms a basis for such a position."

[9] See the '498 patent to Matheson at column 2, lines 53-57.

Applicants' Response:

The Examiner has erred in interpreting the scope and content of Simpson. Applicants' arguments do not "hinge on speculation" because there are in fact three particular disclosures that show why the Simpson flap is not pressed towards the seal surface under any orientation of its valve.

Firstly, the Simpson valve itself shows that there is no preload or bias placed on the flap:

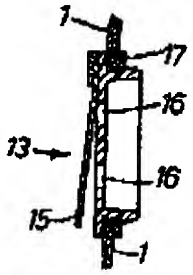

FIG. 2.

As the Board can note, the flap-retaining surfaces is in direct alignment with the seal surface, and there is no other instrument that causes the flap to be pressed towards the seal surface. Therefore, when the valve is inverted, gravity will act upon flap 15 to force it downward. The valve flap — if made from a conventional flap material, which we must assume it is since the patent does not disclose otherwise — will then droop away from the seal surface.

Secondly, Simpson indicates that its valve can leak in the paragraph set forth on page 1, lines 58-64 in the specification:

> To prevent inhalation of harmful atmosphere owing to leakage of the or each valve, the valve may be provided with an antechamber so arranged that, if the valve does leak in operation, the wearer inhales previously exhaled breath and not the harmful atmosphere.

This admission of leakage demonstrates that the flap droops away from the seal surface. Applicants are not aware of any other way in which the flap could leak.

Thirdly, Simpson shows the valve 12 on the top portion of the filtering face piece. In this position, the valve can take advantage of gravity to encourage the flap 15 to remain pressed against the seal surface when a wearer is neither inhaling nor exhaling. If a wearer tips their head downward, however, the advantage of gravity would be lost, and the flap could then droop away from the seal surface.

Previously submitted Affidavits of Dave Castiglione (Exhibit A) and of John Bowers (Exhibit B) both support the position that Simpson's valve could allow for the influx of contaminants because the flap is not pressed against the seal surface in a neutral position. For ease of reference, applicants have reproduced paragraph 9 of the Castiglione Affidavit:

> 9. That I do not agree with the position taken by the Examiner at the bottom of page 3 of the Office Action. My review of the '516 UK patent application leads me to the conclusion that the valve 13 shown in Figure 2 does not have its flap 15 pressed towards the seal surface in an abutting relationship when the wearer is neither inhaling or exhaling. The '516 application reveals two distinctly different valves: a flap valve 13 as shown in Figure 2; and a diaphragm valve 14 as shown in Figure 3. These flaps have distinctly different constructions and operate differently. The [flapper] valve shown in Figure 2 has a flat seal surface. The mounting of the flap 15 to the seal surface at the top or fixed portion of the flap does not show a preload on the flap 15. There is nothing that can be discerned from Figure 2 or from the specification that would indicate that the flap is pressed towards the seal surface in its neutral position. And because Figure 3 shows a flap 18 resting upon the seal surface in the flap's neutral position while Figure 2 shows the flap 15 dangling away from the seal surface in an apparent neutral position also, it can be concluded that the valve 13 of Figure 2 would only become pressed against the seal surface during an inhalation. A review of the '516 UK application thus leads me to believe that the valve shown in Figure 2 is a unidirectional exhalation valve that prevents the influx of contaminants through the exhalation valve during an inhalation when it is most needed. It is not apparent to me that the valve would be pressed towards the seal surface under a neutral condition when the wearer is neither inhaling nor exhaling.

Applicants have also reproduced paragraphs 15 and 16 of the Bowers' Declaration:

> 15. My review of the Simpson document reveals a flapper-style valve 13 in Fig. 2, which would not have its "flexible circular flap member 15" pressed against the valve's seal surface when a wearer of the mask is neither inhaling nor exhaling. The aligned relationship between the flap retaining surface and the seal surface and their relative positioning would not cause Simpson's flap 15 to be pressed against the valve's seal surface. At best the flap 15 would rest flush against the seal surface as a result of its securement at the flap retaining surface. The Simpson valve 13 therefore could allow for the influx of contaminants into the mask interior when, for example, a wearer tilts their head downwards and allows gravity to draw the flap away from the seal surface.
>
> 16. The Simpson product also has the valve located on the upper portion 1 of the pouch-shaped mask. This has the disadvantage that the warm moist exhaled air may be directed towards the eyes, causing misting of the eyewear. And Simpson's Fig. 2 valve cannot be positioned on the underside of the mask because the flap 15 would droop away from contact with the valve seat, causing the valve to leak.

As this testimony reveals, there is no mechanical means for having Simpson's flap 15 pressed against the seal surface. The Bowers' Declaration, in particular, states how the flap could droop away from the seal surface. It is improper for the Examiner to substitute his judgment for that of an expert in the field.[10] The Manual of Patent Examining Procedure explains:

> Evidence traversing rejections must be considered by the Examiner whenever present. All entered affidavits, declarations, and other evidence traversing rejections are acknowledged and commented upon by the examiner in the next succeeding action....*Where the evidence is insufficient to overcome the rejection, the examiner must specifically explain why the evidence is insufficient.* General statements such as 'the declaration lacks technical validity' or 'the evidence is not commensurate with the scope of the claims' without an explanation supporting such findings are insufficient (emphasis added).[11]

Despite the explicit language in the MPEP highlighted above, the Examiner has yet to explain why the evidence furnished by applicants is insufficient. The Examiner only comments on what the Simpson patent does not disclose (and as indicated above, does so erroneously).

15. Examiner's Answer at sentence bridging pages 17 and 18

"In order for the mask of Simpson et al. to function as it is intended (and there is no reason to even suspect that it does not), the exhalation valve (fig. 2) must remain closed until a wearer exhales; otherwise, gaseous or vaporous contaminants would leak into the interior of the mask body and be inhaled by such a wearer."

Applicants' Response:

Again, the Examiner is reviewing the Simpson patent from the perspective of the person who has read applicants' specification rather than from the state-of-the-art that existed at the time the Simpson patent was published. The Examiner also ignores the actual disclosure in the

[10] *See, In re Zeidler*, 215 USPQ 490 (CCPA 1982) ("Although perception of color may, in essence, be a 'subjective' determination, we believe that an expert's evaluation in this field is entitled to more weight than that of a layman. *In re Neave*, 54 CCPA 999, 1007, 370 F.2d 961, 968, 152 USPQ 274, 279-80 (1967) ("Therefore, because the qualifications of Lach and the test procedures which he employed are unchallenged, the board's holding that 'a more dramatic difference in results' is required constitutes reversible error, the board having erroneously substituted its judgment for that of an established expert in the art."); *In re Fay*, 146 USPQ 47 (CCPA 1965) ("It seems to us that one as well qualified in the highly technical art of fluoride-containing halogenated compounds as Henne is shown to be is properly entitled to express his expert opinion, and that such an opinion is entitled to be given consideration with the other evidence in the case in determining whether the conclusion of obviousness is supported by the opinion of the examiner as to what the prior art teaches. For the reasons previously stated we do not think the prior art teachings furnish factual support for the examiner's opinion."); *see also In re Alton*, 37 USPQ2d 1578 (Fed. Cir. 1996) ("We do, however, hold that the examiner's final rejection and Answer contained two errors; (1) viewing the Wall declaration as opinion evidence addressing a question of law rather than a question of fact; and (2) the summary dismissal of the declaration, without an adequate explanation of why the declaration failed to rebut the Board's *prima facie* case of inadequate description.").

[11] MANUAL OF PATENT EXAMINING Procedure § 2144.03, 2100-129 (August 2001).

Simpson patent. Simpson (i) does not impose a preload on its flapper valve 13 shown Figure 2, and Simpson (ii) places the valve 12 on the top portion 1of the mask (figure 1) and (iii) suggests the use of an antechamber to prevent harmful contaminants from leaking into the mask through the exhalation valve (page 1, lines 58-63). For these three reasons, it is clear that the Simpson valve does not remain closed under any orientation of the mask. Thus, although it may be apparent that a person of ordinary skill would design a flapper valve that remained closed under all conditions after reading applicants' specification, it certainly was not apparent to Simpson in 1980. Further, the Simpson mask "does function as intended." It filters harmful contaminants during an inhalation, and the valve precludes contaminants from entering the interior of the mask during an inhalation, which is the most critical time. The Simpson valve nonetheless does leak under other circumstances. Simpson explicitly admits this (p. 1, lines 58-63). Thus, the Examiner's position does not come from Simpson but rather is an unsupported viewpoint.

16. Examiner's Answer at page 18, 2nd full paragraph

"Further, the question of whether McKim constitutes non-analogous art has been addressed and settled in a previous appeal to the Board of Appeals in appellants' related application 08/240,877 in which the Board of Appeals upheld the prior art combination of McKim with other prior art references including Simpson et al."

Applicants' Response:

Once again the Examiner has mischaracterized the record. The Board of Patent Appeals and Interferences has never dealt with the issue of whether McKim constitutes non-analogous art. That issue was never raised in application 08/240,877. Therefore, it was never decided. Applicants never argued that McKim was non-analogous, and the Board made no ruling on the issue in their decision. Further, the claims that were present in 08/240,877 are distinctly different from the claims that are present on appeal in this case. In addition, the evidence presented in the Castiglione, Bowers, Fabin, and Betts' Declarations was not of record in the '877 case. In short, the issue was never presented, never decided, and even if it was, it would not be pertinent to the present case because the claims are different and additional evidence is now of record.

For the reasons submitted above and those presented in their Appeal Brief, applicants believe that the decision below should be reversed.

Respectfully submitted,

February 11, 2004
Date

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